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Aeroneb Solo® System Instruction Manual

Aeroneb® Solo System Instruction Manual

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Introduction

The Aeroneb® Solo System is an iteration of the Aeroneb® Professional Nebulizer System. The indications for use of the Aeroneb® Solo Nebulizer System are given below. The Aeroneb® Solo System consists of the Aeroneb® Solo nebulizer and the Aeroneb® Pro-X controller. It is intended for hospital use only to nebulize physician-prescribed medications for inhalation which are approved for use with a general purpose nebulizer. The Aeroneb Solo nebulizer is for single patient use only and the Aeroneb® Pro-X controller is for re-use.

The Aeroneb Solo System is suitable for intermittent and continuous nebulization of pediatric (29 days or older) and adult patients as described in this manual.

Indications for Use

The Aeroneb Solo Nebulizer System is a portable medical device for single patient use that is intended to aerosolize physician-prescribed solutions for inhalation to patients on and off ventilation or other positive pressure breathing assistance.

Aeroneb® Solo System

The Aeroneb Solo System includes the following components:

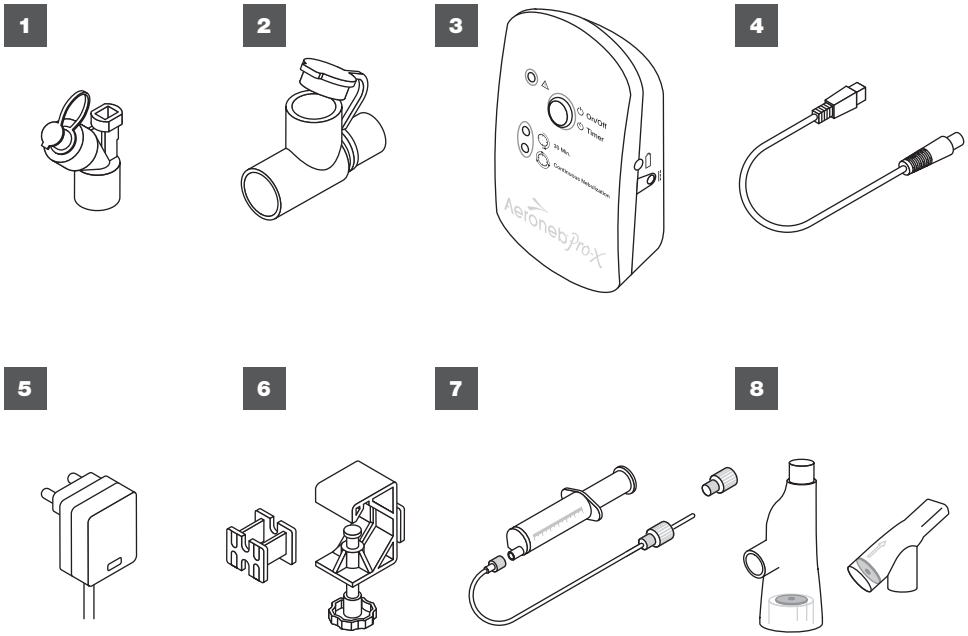


Figure 1. Aeroneb Solo System

1. Aeroneb Solo With Plug
2. T-Piece (Adult)*
3. Aeroneb Pro-X Controller
4. Controller Cable
5. AC/DC Adapter
6. Universal Mounting Bracket & Equipment Mount Adapter
7. Continuous Nebulization Tube Set*
8. Aeroneb Solo Adapter*

***** Pediatric adapters, continuous nebulization tube set and Aeroneb Solo Adapter are sold separately.

System Warnings

Read and study all instructions before using the Aeroneb Solo system and accessories. Only trained medical personnel should operate the device.

This is a single patient use device not to be used on more than one patient to prevent cross infection.

The components and accessories of the Aeroneb Solo system, as packaged, are not sterile.

Inspect all system and accessory parts before use. Do not use if any parts are missing, cracked or damaged, or if there is any foreign matter present. In such cases, contact your Aerogen product sales representative.

Only use physician-prescribed solutions that are approved for use with a general purpose nebulizer. Consult drug manufacturer's instructions regarding suitability for nebulization.

Use only with Aeroneb Solo components, connectors and accessories specified by Aerogen in this manual.

Do not use beyond defined life (see page 13 for Aeroneb Solo Adapter and page 24 for Aeroneb Solo System).

To avoid the risk of fire, do not use in the presence of flammable substances or flammable anaesthetic mixtures combined with air, oxygen or nitrous oxide.

Do not use the Aeroneb Solo in conjunction with the administration of volatile anaesthetics as this may have an adverse effect on the Aeroneb Solo nebulizer or T-piece plastics.

Do not use to aerosolize alcohol-based medications, which can ignite in oxygen-enriched air under high pressure.

Do not autoclave any component or accessory of the Aeroneb Solo system.

Do not modify this equipment without authorization from the manufacturer.

To avoid damage to the nebulizer:

- Do not apply undue pressure to the domed aperture plate in the center of the nebulizer.
- Do not push out the vibrating mesh aerosol generator.
- Do not use a syringe with a needle to add medication.
- Do not attempt to clean the nebulizer

Do not use or store outside of specified environmental conditions.

Federal (US) Law restricts this device to sale by or on the order of a physician.

Assembly & Installation

Aeroneb Solo System Set-Up

Perform a functional test of the Aeroneb Solo before use as described in the Functional Test section of this manual (See page 18).

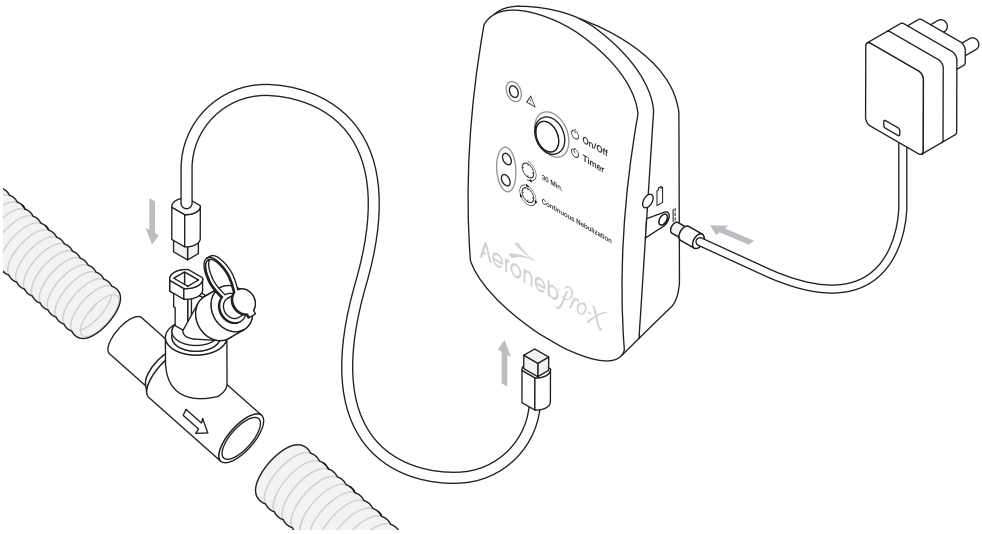
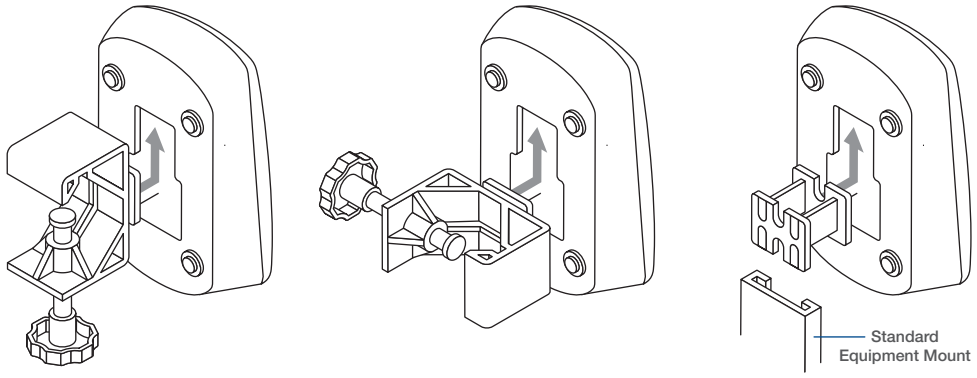


Figure 2. Assembly of Aeroneb Solo System

1. Connect the Aeroneb Solo to the T-piece by pushing the nebulizer firmly onto the T-piece.
2. Insert the Aeroneb Solo and the T-piece into the breathing circuit with the arrow on the T-piece pointing in the direction of the air-flow within the circuit. **Note:** For use with other accessories, refer to Figure 8, Figure 9 and Figure 10.
3. Connect the Aeroneb Pro-X controller to the Aeroneb Solo using the nebulizer cable.
4. To operate on AC power (the primary mode of operation), connect the Aeroneb Pro-X AC/DC adapter to the Aeroneb Pro-X controller.
5. Plug the adapter into an AC power source.
6. Aeroneb Pro-X can be battery-operated for portable applications. The rechargeable battery can power the System for up to 45 minutes when fully charged. In the case of AC power failure the controller will automatically switch to battery operation.

7. Use the universal mounting bracket to attach the controller to an IV pole or bed rail in either a vertical or horizontal orientation (Figure 3).
8. Where a standard equipment mount is available, use the equipment mount adapter to support the controller (Figure 3).



Vertical
Universal Mounting Bracket

Horizontal
Universal Mounting Bracket

Equipment
Mount Adapter

Figure 3. Aeroneb Pro-X Controller and universal mounting bracket configurations

Warnings

- To ensure uninterrupted operation of the Aeroneb Solo, secure both the AC/DC adapter cable and the controller cable so they cannot become disconnected during treatment. If clips are available on patient circuits, run the cables through the eyes of the clips. If clips are not available, ensure that all cables are routed safely.
- The AC/DC adapter is the means of isolating the Aeroneb Solo system from the mains power supply.
- The continuous mode can only be operated from AC power supply.
- Do not over-tighten knob on the universal mounting bracket.

Aeroneb Pro-X Controller

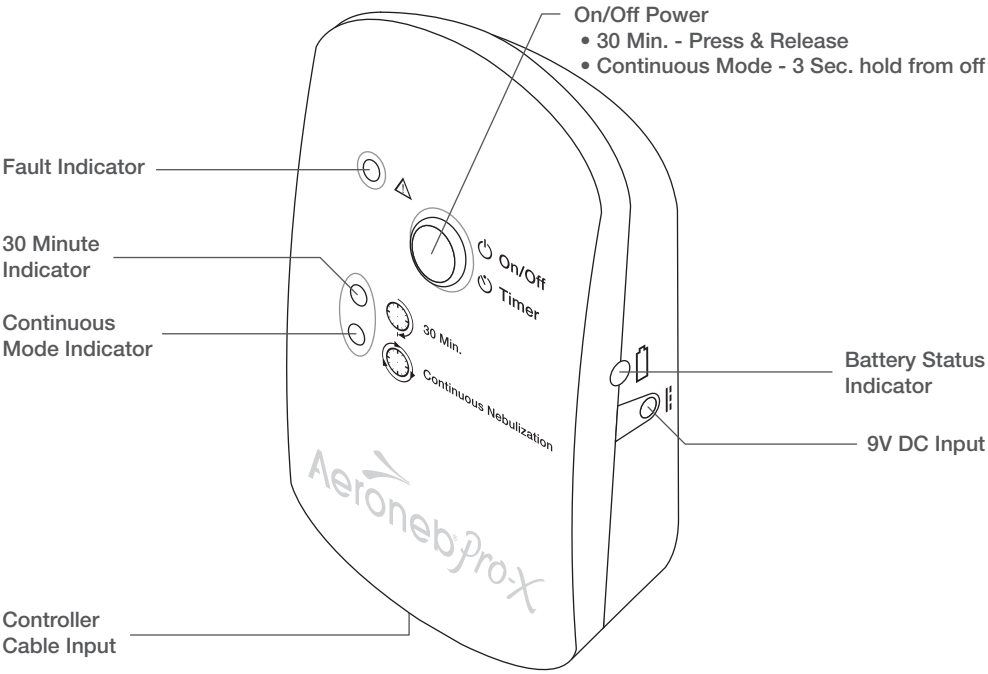


Figure 4. Aeroneb Pro-X Controls & indicators

Table 1. Aeroneb Pro-X Controls & Indicators

Control / Indicator	Function
30 Min. Indicator	• Green (steadily lit) = 30 minute nebulization cycle on • Green (flashing) = Low battery power • Nebulizer automatically powers off after 30 minutes have elapsed
Continuous Indicator	• Green (steadily lit) = Continuous nebulization cycle on • Nebulizer does not power off automatically
Fault Indicator	• Amber (steadily lit) = Aeroneb Solo nebulizer disconnected from Aeroneb Pro-X controller • Amber (flashing) = Aeroneb Pro-X drive voltage error
On/Off Power Button	• To operate in 30 minute mode press the On/Off button once • To operate in continuous mode press and hold the On/Off button for greater than 3 seconds from off • Pressing during nebulization turns off power to the nebulizer
Battery Status Indicator	• Green = Battery fully charged. • Amber = Battery charging. • No light = Battery in operation.

Recharging the Battery

To recharge the battery, connect the AC/DC adapter to the controller and connect to AC power source. The battery status indicator is amber while charging and green when fully charged.

If the controller is placed in long-term storage, it is recommended that the battery be recharged every 3 months.

Allow a minimum of four hours for the internal battery to fully recharge.

Cleaning the Pro-X Controller

Cleaning of controller and controller cable, AC/DC adapter and mounting brackets:

1. Wipe clean with an alcohol based disinfectant wipe or a quaternary ammonium compound based disinfectant wipe.
2. Check for exposed wiring, damaged connectors, or other defects and replace controller if any are visible.
3. Visually inspect for damage and replace the controller if any damage is observed.

Warnings

- Do not immerse or autoclave the Aeroneb Pro-X Controller, cable or AC/DC adapter.
- Do not place the Aeroneb Pro-X in an incubator during use.
- Do not use abrasive or sharp tools.
- Do not spray liquid directly onto the controller.
- Do not wrap the nebulizer cable tightly around any of the system components.
- Do not use in the presence of devices generating high electromagnetic fields such as magnetic resonance imaging (MRI) equipment.
- The Aeroneb Pro-X controller contains a nickel metal hydride (NiMH) rechargeable battery, which should be disposed of in accordance with local governing regulations at the end of its useful life.
- Follow local laws and recycling plans regarding disposal or recycling of components, batteries and packaging.

Installation for use with a Ventilator

T-Pieces - Connection to a Breathing Circuit

1. For 22mm adult breathing circuits connect the nebulizer with adult T-piece into the inspiratory limb of the breathing circuit before the patient Y (Figure 5).

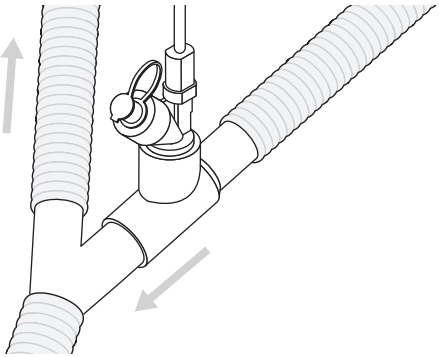


Figure 5. Connecting the Aeroneb Solo to a breathing circuit

Note: Figure 5 shows adult configuration only

For 15mm ***pediatric breathing circuits*** connect the nebulizer with the pediatric T-piece into the inspiratory limb of the breathing circuit before the patient Y.

The Aeroneb Solo can connect to 10mm ***pediatric breathing circuits*** with the 15mm pediatric T-piece and the pediatric adapters. This can be positioned approximately 30 cm (12 in.) back from the patient Y (Figure 6).

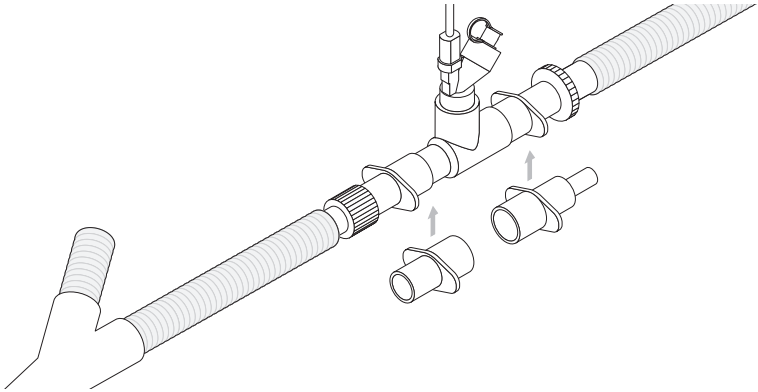


Figure 6. Connecting to a pediatric breathing circuit

2. The Aeroneb Solo can be placed on the dry side of the humidifier as shown in Figure 7. The Aeroneb Solo can be used with a nasal interface in this configuration.

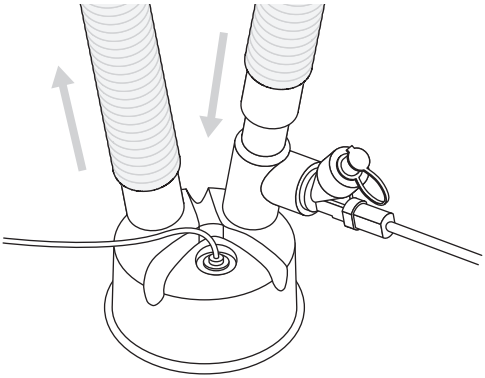


Figure 7. Aeroneb Solo on dry side of humidifier

3. Follow ventilator manufacturer instructions for performing a leak test after inserting or removing the nebulizer.

Warnings

- Condensate can collect and occlude ventilator circuits. Always position ventilator circuits so that fluid condensate drains away from the patient.
- Always connect a bacteria filter to the expiratory inlet of the ventilator. Otherwise the function of the expiratory channel may be degraded.
- Do not use a filter or heat-moisture exchanger (HME) between the nebulizer and patient airway.

Installation for use Off-Ventilator

Use with a Facemask

Mask kits, which include a vented elbow and mask elbow, are available separately (see part numbers page 22).

1. When using a mask, connect the vented elbow, mask elbow and mask to the nebulizer by firmly pushing the parts together.
2. Rotate the vented elbow to suit the position of the patient (Figure 8).

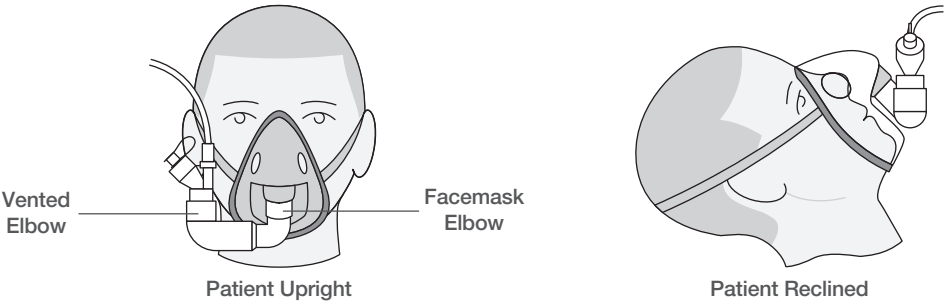


Figure 8. Connecting to a mask

Use with a Mouthpiece

The Aeroneb Solo is compatible with any standard ISO 22 mm nebulizer mouthpiece inserted into the adult T-piece.

When using a mouthpiece, connect the nebulizer to the T-piece and then connect the T-piece to the mouthpiece by pushing the parts firmly together as shown in Figure 9.

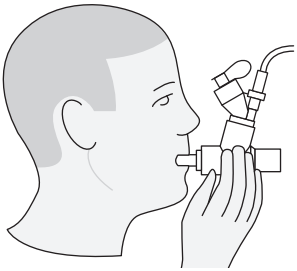


Figure 9. Connecting to a mouthpiece

Warning: To ensure correct nebulization, maintain the nebulizer in a vertical orientation (Figure 8 & Figure 9)

Use with a Nasal Interface

The Aeroneb Solo can be used on/off ventilator with a nasal interface when configured with a humidifier (Figure 7).

Aeroneb Solo Adapter

The Aeroneb Solo Adapter is an accessory specific to the Aeroneb Solo nebulizer. It facilitates intermittent and continuous nebulization and optional supply of supplemental oxygen to pediatric (29 days or older) and adult patients in hospital use environments via mouthpiece or aerosol facemask. If supplemental oxygen is used, for pediatric patients under 18 years of age, a maximum flow rate of 2 LPM should be used.
Note: The mouthpiece should not be used for children under 5 years of age.

The Aeroneb Solo Adapter is a single patient use device with a validated defined life of:

- In intermittent use for a maximum of 20 treatments; which is based upon a typical usage profile of four 3ml doses per day over 5 days, with an average treatment time of 9 minutes.
  or
- In continuous use, for a maximum of 3 hours.

The Aeroneb Solo Adapter can be used in conjunction with the Aeroneb Solo Continuous Nebulization Tube Set (see page 16).

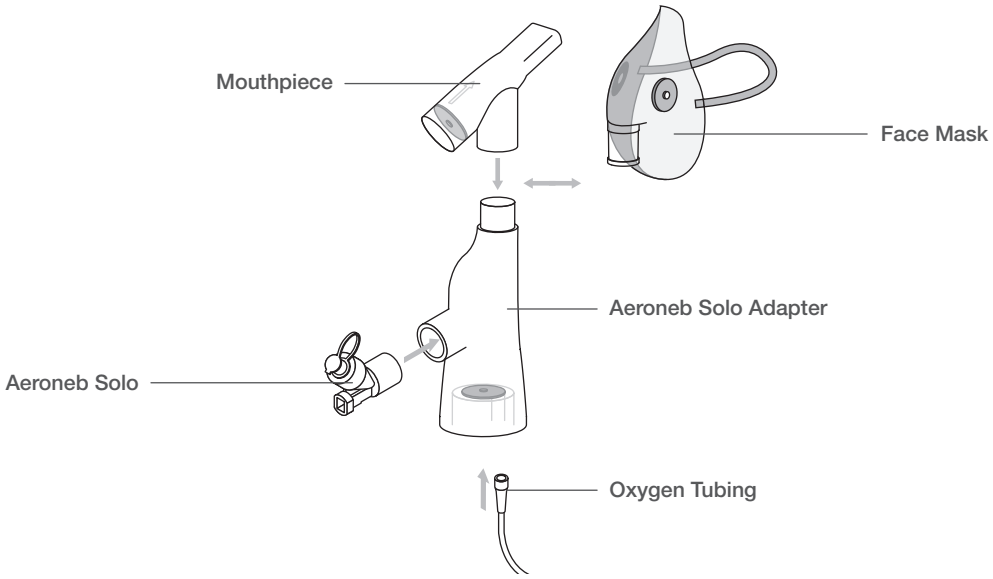


Figure 10. Assembly of Aeroneb Solo Adapter

Optimal aerosol delivery is achieved with valved mouthpiece or valved facemask with low/no oxygen flow. A facemask is not provided.

Inspect for device integrity and correct valve placement prior to use.

1. Insert Aeroneb Solo nebulizer firmly into Adapter in orientation shown in Figure 10.
2. If supplemental oxygen is required, firmly attach oxygen tubing to Adapter.
   Note: Oxygen flow rate should be set between 1-6 LPM for adult and a maximum of 2 LPM for pediatric patients less than 18 years of age.
3. If an aerosol facemask is required, remove mouthpiece and attach the aerosol facemask to Adapter.
   Note: When using an aerosol face mask, a minimum oxygen flow of 1 LPM is required.
4. Add medication to nebulizer.
5. Connect cable to Aeroneb Solo and power on controller.
6. Introduce Adapter to patient and observe aerosol flow to ensure correct operation.
7. Remove excess rainout from Adapter periodically (hourly with continuous nebulization).
8. To ensure optimum performance of the Adapter, remove any residue by rinsing through with sterile water, shake off excess and allow to air dry.

Warnings

- Do not use with a closed face mask or a standard oxygen mask.
- When using with an aerosol face mask, always use supplemental oxygen flow of 1-6 LPM for adult and a maximum of 2 LPM for pediatric patients less than 18 years of age.
- Performance of the Adapter may vary depending upon the type of drug and Adapter configuration used.
- Do not exceed recommended oxygen flow for system.
- Ensure oxygen connection port or tubing is not occluded.
- Do not use Adapter without a mouthpiece or facemask.
- Visually check Adapter post-rinsing to ensure that valves have not become dislodged.
- Do not cover Adapter valves during use.
- Do not use Adapter in conjunction with the Aeroneb Pro nebulizer.
- Do not autoclave any component of the kit.
- Ensure tubing is safely orientated to prevent strangulation hazard.

Nebulization Modes

Intermittent Mode

Warnings

- To avoid damage to the Aeroneb Solo, do not use a syringe with needle.
- During use observe for correct functioning of the nebulizer.
- The maximum capacity of the nebulizer is 6 mL.

For intermittent doses less than or equal to 6 mL:

1. Open the plug on the nebulizer.
2. Use a pre-filled ampoule or syringe to add medication into the filler port of the nebulizer (Figure 11).
3. Close the plug.

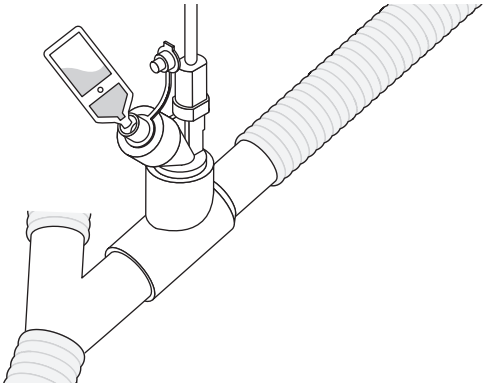


Figure 11. Filling the nebulizer with a pre-filled ampoule

4. To start a 30 minute nebulization cycle, press and release the blue on/off power button (Figure 4). The green 30 minute indicator light illuminates to indicate that the 30 minute nebulization cycle is in progress.
5. To stop the nebulizer at any time, press the on/off power button. The indicator turns off to indicate that nebulization has stopped.

Note: Medication can be added to the Aeroneb Solo during nebulization. This does not interrupt nebulization or ventilation.

Continuous Mode

Continuous Nebulization Tube Set

The Aerogen Continuous Nebulization Tube Set is an accessory specific to the Aeroneb Solo nebulizer which enables safe continuous infusion of liquid medication for aerosolization.

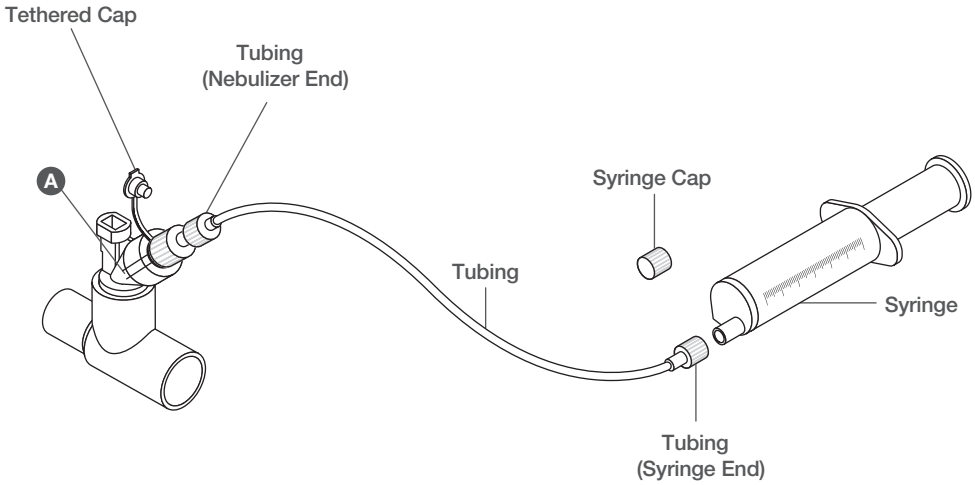


Figure 12. Continuous Nebulization Tube Set

Note: Place the syringe cap on the syringe after it is filled with medication.

1. Ensure the Aeroneb Solo nebulizer is firmly fitted into the Aeroneb Solo T-piece in the breathing circuit.
2. Remove the syringe cap from the medication-filled syringe.
3. Attach the syringe end of the tubing onto the syringe.
4. Prime the tubing until the medication reaches end of tubing (Point A).
   Note: The tubing priming volume is maximum 3.65 mL.
5. Unplug the tethered cap from the Aeroneb Solo nebulizer, but do not remove it from the nebulizer.
6. Screw the nebulizer end of the tubing onto the top of the nebulizer.
7. Insert the syringe filled with medication into the syringe infusion pump (pump not shown in Figure 12) and set the appropriate flow rate (refer to pump manual or manufacturer for guidance).

8. To start a continuous nebulization cycle, press and hold the blue On/Off power button from the off state for at least three seconds. Verify the green, 'continuous nebulization' indicator light is on (Figure 4).
9. Observe nebulizer for correct operation. During continuous nebulization, the nebulizer is on continuously and the medication is nebulized on a drop by drop basis. Nebulization should be visible with regular intermittent pauses. Medication level in the nebulizer reservoir should not rise during use.
10. To stop the nebulizer at any time, press the on/off power button. The indicator turns off to indicate that nebulization has stopped.

Aerogen's recommended input rate of medication into the Aeroneb Solo nebulizer during continuous nebulization is up to a maximum of 12 mL per hour. The upper limit of 12 mL per hour is based on Aerogen's specification for the minimum nebulizer flow rate. For directions on determining flow rates, refer to the Optional Flow Rate Calculation method in the Functional Test section, page 19.

Warnings Specific to the Continuous Nebulization Tube Set

- It is important to ensure that the maximum flow rate through the tube set into the nebulizer must not exceed the output rate of the nebulizer.
- Check for leaks from the system prior to and during use.
- The graduations on the syringe are for indication use only.
- Store at room temperature and use product within labelled shelf life.
- To ensure correct and safe connection between the nebulizer and the medication reservoir, trace the medication tube from the nebulizer back to the medication reservoir to make sure the medication tube is connected to the correct source.
- The recommended syringe pump software setting with the Aerogen syringe is typically the "BD Plastipak" setting. This must be validated locally before use. Refer to pump manual or manufacturer for guidance. These pumps may also be used in accordance with local hospital or ward policies.
- Ensure that the tethered silicone plug is attached to the Aeroneb Solo when connecting tube set.
- Ensure that the tubing is safely orientated to prevent a trip hazard.
- Rising level of medication in the reservoir may occur if the Aeroneb Solo nebulizer is turned off while the feed system is still on or the nebulizer is not in its recommended orientation.
- The level of the medication in the reservoir of the Aeroneb Solo nebulizer should be periodically monitored to ensure that the fill rate of medication does not exceed the output rate of the nebulizer. A rising level of medication in the reservoir indicates that the fill rate is exceeding the output rate of the nebulizer.
- Replace the tube set and syringe when changing the type of medication.

- Do not connect the tube set and syringe to non-respiratory equipment.
- Do not clean or sterilize.
- Do not connect to any nebulizer other than the Aeroneb Solo.

Note: If the mains power is disconnected during a continuous nebulization cycle and reconnected within 10 seconds, the controller shall return to continuous nebulization mode automatically.

Functional Test

Perform a functional test of the Aeroneb Solo System prior to first use or at any time to verify proper operation. This test is to be carried out prior to inserting the neb into a circuit or accessory.

1. Visually inspect each part of the System for cracks or damage and replace if any defects are visible.
2. Pour 1-6 mL of normal saline (0.9%) into the nebulizer.
3. Connect the nebulizer to the controller using the controller cable. Connect the AC/DC adapter to the controller and plug the AC/DC adapter into an AC power source.
4. Press and release the blue on/off power button and verify that the green 30 Min. indicator light illuminates and that aerosol is visible.
5. Disconnect the AC/DC adapter from the controller and verify that nebulization continues and that the battery status indicator turns off.
6. Power off the controller. Reconnect the AC/DC adapter to the controller. Press and hold the button for at least three seconds. Verify that the green Continuous indicator light illuminates and that aerosol is visible.
7. Turn the System off and verify that the 30 Min. and Continuous indicators are off.

Aeroneb Solo Aerosol Flow Rate Calculation

Flow rates may vary between individual Aeroneb Solo nebulizers. The minimum flow rate for all Aeroneb Solo nebulizers is 0.2 mL per minute. In order to calculate the flow rate of an individual Aeroneb Solo nebulizer:

1. Transfer 0.5 mL of normal saline (0.9%) or intended drug into the Aeroneb Solo medication cup.
2. Turn on the nebulizer.
3. Using a stop-watch, measure the length of time it takes from the start of nebulization until all the saline/drug has been nebulized.
4. Calculate the flow rate using the following equations:

$$\text{Flow rate in mL/min} = \left(\frac{\text{Volume of normal saline or drug}}{\text{Nebulization time in seconds}} \right) \times 60$$

$$\text{Flow rate in mL/hr} = \left(\left(\frac{\text{Volume of normal saline or drug}}{\text{Nebulization time in seconds}} \right) \times 60 \right) \times 60$$

Troubleshooting

If these suggestions do not correct the problem, discontinue use of any device that appears to be damaged or is not operating properly and contact your local Aerogen product sales representative.

Table 2. Aeroneb Pro-X Troubleshooting

If this happens:	It could mean:	Try this:
The 30 Min. indicator flashes during nebulization.	Battery power is low.	Recharge battery (see Recharging the battery).
Battery will not recharge. Controller is connected to the AC/DC adapter and the battery charging light is illuminated green and the 30 Min. indicator light is flashing.	It may be time to replace the battery.	Contact your local Aerogen product sales representative.
Battery will not retain initial charge.	Rechargeable battery may need to be replaced.	Contact your local Aerogen product sales representative.
The 30 Min. or Continuous light illuminates, but aerosol is not visible.	No medication in nebulizer.	Refill medication through filler cap in the nebulizer (see page 15).
	It may be time to replace the nebulizer.	See Warranty and Life of Product. Refer to Aeroneb Solo parts list.
30 Min. or Continuous indicator does not light when on/off power button is pressed.	There is no power to the System.	Verify that AC/DC adapter is securely attached to controller.
	Rechargeable battery is depleted.	Recharge battery (see Recharging the battery).

Table 2. Aeroneb Pro-X Troubleshooting (Continued)

If this happens:	It could mean:	Try this:
The fault indicator light illuminates.	The controller cable is incorrectly connected to the nebulizer, or electronics are malfunctioning.	Verify that controller cable is correctly connected to both the nebulizer and the controller.
Medication is left in the nebulizer after nebulization cycle.	Nebulizer was not turned on or connected to power.	Ensure that nebulizer is connected to power and turned on.
	Rechargeable battery is depleted.	Recharge battery (see Recharging the battery).
	A 30 minute cycle was selected when connected to the continuous feed system.	Run a continuous cycle.
	It may be time to replace the nebulizer.	See Warranty and Life of Product. Refer to Aeroneb Solo parts list.
Flashing amber light.	It may mean that it is time to replace controller.	Contact your local Aerogen Product sales representative.

Note: The rechargeable battery in the Aeroneb Pro-X controller should only be replaced by Aerogen authorized personnel: contact your Aerogen product sales representative.

Parts List

Table 3. Aeroneb Solo System Part Numbers

Description	Part Number
Aeroneb Solo Starter Kit • Aeroneb Solo nebulizer (x 2) • Adult T-piece with silicone plug (x 2) • Aeroneb Pro-X Controller • Universal Mounting Bracket • AC/DC Adapter • Instruction Manual	AG-AS3000-US
Aeroneb Solo Convenience Kit - Pack of 5 • Aeroneb Solo nebulizers • Adult T-pieces with silicone plugs	AG-AS3300-US
Aeroneb Solo Convenience Kit - Pack of 10 • Aeroneb Solo nebulizers • Adult T-pieces with silicone plugs	AG-AS3350-US
Aeroneb Solo Nebulizers - Pack of 5	AG-AS3100
Aeroneb Solo Nebulizers - Pack of 10	AG-AS3200
Disposable Adult T-piece - Pack of 10 • 22M - 22F - 22M	AG-AS3010
Disposable Pediatric T-piece - Pack of 10 • 15M - 22F - 15M	AG-AS3020
Disposable Pediatric T-piece Adapter Kit - Pack of 10 • T-Piece: 15M - 22F - 15M • Adapters: 15M - 10M/ 7.5M 15F - 10M/ 7.5F	AG-AS3025
Disposable Pediatric T-piece - Pack of 10 • 12M - 22F - 12F (Fits Fisher & Paykel Circuit)	AG-AS3035
Disposable Pediatric T-piece - Pack of 10 • 10M - 22F - (Fits SLE Circuit)	AG-AS3036
T-piece Silicone Plug For use with: AG-AS3010, AG-AS3020, AG-AS3025 & AG-AS3036	AG-AS3450
Disposable Mask Kit (US) - Pack of 5 • 22M - 17M/18.5M • 22F - 22F (vented)	AG-AS1065
Disposable Mask Kit (International) - Pack of 5 • 22F - 22M/15F • 22F - 22F (vented)	AG-AS1075
Disposable Vented Elbow - Pack of 5 • 22F - 22F (vented)	AG-AS1055

Table 3. Aeroneb Solo System Part Numbers (Continued)

Description	Part Number
Continuous Nebulization Tube Set Tubing - Pack of 5	AG-AS3075
Continuous Nebulization Tube Set Syringe (60mL)- Pack of 5	AG-AS3085
Continuous Nebulization Tube Set Syringe (60mL) - Pack of 50	AG-AS3095
AC/DC Adapter	AG-AP1040-US
Aeroneb Pro-X Controller	AG-PX1050-US
Controller Cable	AG-AP1085
Universal Mounting Bracket	AG-AP1060
Equipment Mount Adapter	AG-AP1070
Aeroneb Solo Starter Kit Instruction Manual	AG-AS3050-US
Aeroneb Solo Adapter Starter Kit – Pack of 10	AG-AS7500-US
Aeroneb Solo Adapter – Pack of 10	AG-AS7000-US

Warranty

Aerogen warrants that the Aeroneb Solo nebulizer shall be free from defects of workmanship and materials for a period of the defined life of the nebulizer when used in accordance with this instruction manual.

The Aeroneb Pro-X Controller and AC/DC Adapter are warranted against defects in manufacturing for a period of two years from the date of purchase. All warranties are based on typical usage, detailed below.

Life of Product

As with all active electronic components, the Aeroneb Solo nebulizer has a defined life. In the case of Aeroneb Solo, the life of the nebulizer has been validated for intermittent use for a maximum of 28 days based upon a typical usage profile of 4 treatments per day.

For continuous use the life of the Aeroneb Solo nebulizer and the continuous nebulization tube set have been qualified for use for a maximum of 7 days.

The user should note that use in excess of these periods is not qualified by Aerogen.

Specifications

Table 4. Physical Specification of the Aeroneb Solo System

Nebulizer Dimensions	67 mm H x 48 mm W x 25 mm D 2.6” H x 1.88” W x 1.1” D
Aeroneb Pro-X Controller Dimensions	33mm H x 75mm W x 131mm D 1.3” H x 2.9” W x 5.2”D
Controller Cable Length	1.8 m (5.9 ft.)
AC/DC Adapter Cable Length	2.1 m (6.7 ft.)
Nebulizer Weight	13.5 g (0.5 oz) nebulizer and plug
Aeroneb Pro-X Controller Weight	230 g (8.1 oz.), including battery and cable
Nebulizer Capacity	Maximum 6 mL

Table 5. Environmental Specifications of the Aeroneb Solo System

Operating	Maintains specified performance at circuit pressures up to 90 cm H_2O and temperatures from 5 °C (41°F) up to 45 °C (113°F).	
	Atmospheric Pressure	450 to 1100 mbars
	Humidity	15% to 95% relative humidity
	Noise Level	< 35 dB measured at 0.3 m distance
Storage & Transport	**Transient Temperature Range**	-20 to +60°C (-4 to +140°F)
	Atmospheric Pressure	450 to 1100 mbars
	Humidity	15 to 95% relative humidity

Table 6. Power Specifications of the Aeroneb Solo System

Power Source	FRIWO (AG-AP1040-US) AC/DC adapter (input 100 to 240 VAC 50 – 60 Hz, output 9 V) or internal rechargeable battery (4.8 V nominal output). **Note:** The Aeroneb Pro-X controller is approved for use with Aerogen AC/DC adapter AG-AP1040-US (Manufacturer Reference: FRIWO FW7660/09)
Power Consumption	< 8 Watts (charging), 2.0 Watts (nebulizing).
Patient Isolation	Controller circuitry provides 4 kilovolt (kV) patient isolation and complies with IEC/EN 60601-1.

Performance

Table 7. Performance Specifications of the Aeroneb Solo

Flow Rate	> 0.2 mL/min (Average ~ 0.38 mL/min)
Particle Size	**As measured with the Andersen Cascade Impactor:** • Specification Range: 1-5 µm • Average Tested: 3.1 µm **As per EN 13544-1:** • Aerosol Output rate: 0.30 mL/min • Aerosol Output: 1.02 mL emitted of 2.0 mL dose • Residual volume: <0.1 mL for 3 mL dose
Performance may vary depending upon the type of drug and nebulizer used. For additional information contact Aerogen or drug supplier.	
The temperature of the medication will not rise more than 10°C (18°F) above ambient during normal use.	

Table 8 shows the results of aerosol performance testing for the Aeroneb Solo using an 8 stage cascade impactor running at a continuous flow rate of 28.3 LPM. Indicated ranges correspond to confidence intervals with a confidence level of 95%.

Table 8. Aeroneb Solo Aerosol Performance Testing

	Albuterol Sulphate (1mg/ml)	Budesonide (0.5mg/ml)	Ipratropium (0.25mg/ml)
Particle size (µm)	2.90 - 3.23	3.07 - 3.42	3.45 - 3.79
Geometric Standard Deviation (GSD)	2.09 - 2.35	1.80 - 1.93	1.92 - 2.14
Emitted Dose (% of fill)	97.23 - 99.30	97.61 - 98.64	94.12 - 97.84
Respirable Dose (0.5 – 5.0 µm) (% of fill)	67.66 - 73.50	71.78 - 76.69	62.32 - 66.90
Coarse particle Dose (>4.7 µm) (% of fill)	27.00 - 31.11	23.62 - 28.21	32.31 - 36.12
Fine particle Dose (<4.7 µm) (% of fill)	66.33 - 72.07	68.58 - 73.84	59.36 - 64.17
Ultra-fine Particle Dose (<1.0 µm) (% of fill)	5.91 - 9.93	1.85 - 4.19	2.36 - 4.51

Table 9 shows the Inhaled Dose (%) for the Aeroneb Solo Nebulizer and Adapter with supplemental gas flow, measured on a breathing simulator.

Table 9. Inhaled Dose (%) for the Aeroneb Solo and Adapter

Gas Flow Rate (LPM)	Breathing Profile	Patient Interface		
		Mouthpiece	Open Facemask	Valved Facemask
0	Adult	73.5 – 61.6	N/A	70.7 – 52.3
	Pediatric	54.5 – 45.6	N/A	52.9 – 42.5
2	Adult	73.8 – 59.2	44.0 – 37.7	65.4 - 45.3
	Pediatric	55.2 – 40.9	34.4 – 29.2	42.4 - 34.7
6	Adult	52.1 – 47.3	41.6 – 34.7	48.4 – 39.5
Results are Inhaled Dose %, expressed as a % of the Nominal Dose placed in the Aeroneb Solo Nebulizer, across a range of supplemental gas flows. The results provided are the maximum and minimum values for 3 devices tested at each flow rate with each interface.				
Adult Profile: 500ml Vt, 15BPM, 1:1 I:E; Pediatric Profile: 155ml Vt, 25 BPM, 1:2 I:E.				

Symbols

Table 10. Aeroneb Solo System Symbols

Symbol	Meaning	Symbol	Meaning
YYXXXXX	Serial number designation, where YY is the year of manufacture and XXXXX is the serial number		Transient storage temperature limitations –20 °C to +60 °C
	Attention, consult accompanying documents	QTY	Quantity (Number of units contained in package)
	Degree of protection against dripping water	Rx Only	Federal (US) Law restricts this device to sale by or on the order of a physician
	Class II equipment per IEC/EN 60601-1		Certified by TUV with respect to electric shock, fire and mechanical hazards
	Type BF equipment per IEC/EN 60601-1		Controller Input – DC voltage
	On/Off power button (standby)		Controller Output – AC voltage
	30 minute operating mode		Output
	Continuous operating mode		Battery status indicator
	Refer to instruction manual/booklet		

Appendix 1

Electromagnetic Susceptibility

This device meets the requirements of the Electromagnetic Compatibility (EMC), pursuant to the Collateral Standard, IEC/EN 60601-1-2, which addresses EMC in North America, Europe and other global communities. This includes immunity to radio frequency electric fields and electrostatic discharge, in addition to the other applicable requirements of the standard. Compliance with EMC standards does not mean a device has total immunity; certain devices (cellular phones, pagers, etc.) can interrupt operation if they are used near medical equipment. Follow institutional protocol regarding the use and location of devices that could interfere with medical equipment operation.

Note: This device is classified as Class II Type BF medical electrical equipment and the device complies with specified safety levels for electrical isolation and leakage current. The Aeroneb Solo AC/DC adapter (AG-AP1040-US) has no connection to earth ground because the necessary level of protection is achieved through the use of double insulation.

Warnings

- Only use the Aeroneb Solo nebulizer with components specified in the Instruction Manual. Use of the Aeroneb Solo nebulizer with components other than those specified in the Instruction Manual may result in increased emissions or decreased immunity of the Aeroneb Solo nebulizer system.
- Do not use the Aeroneb Solo adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in this configuration.
- The Aeroneb Solo needs special precautions regarding electromagnetic compatibility (“EMC”) and must be installed and put into service according to the EMC information provided in the Instruction Manual.
- Portable and mobile radio frequency (“RF”) communication devices can disrupt medical electrical equipment.

Appendix 1: EMC Tables

The following tables are provided in accordance with IEC/EN 60601-1-2:

Guidance and manufacturer's declaration – electromagnetic emissions		
The Aeroneb Solo nebulizer system is intended for use in the electromagnetic environment specified below. The customer or the user of the Aeroneb Solo nebulizer system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The Aeroneb Solo nebulizer system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Aeroneb Solo nebulizer system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000 3 2	Compliant	
Voltage fluctuations/ flicker emissions IEC 61000 3 3	Compliant	

Recommended separation distances between portable and mobile RF communication equipment and the Aeroneb Solo nebulizer system			
This Aeroneb Solo nebulizer system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Aeroneb Solo nebulizer system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Aeroneb Solo nebulizer system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz d = [1.17] √P	**80 MHz to 800 MHz d = [1.17] √P**	**800 MHz to 2.5 GHz d = [2.33] √P**
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.37**	**0.37**	**0.75**
1	**1.17**	**1.17**	**2.33**
10	**3.70**	**3.70**	**7.36**
100	**11.70**	**11.70**	**23.30**
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer **Note 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and manufacturer's declaration – electromagnetic immunity			
This Aeroneb Solo nebulizer system is intended for use in the electromagnetic environment specified below. The customer or the user of the Aeroneb Solo nebulizer system should assure that it is used in such an environment.			
Immunity Test	**IEC/EN 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC/EN 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±1 kV line(s) to line(s) ±2 kV Line(s) to earth	±1 kV line(s) to line(s) ±2 kV Line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut(60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut 60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Aeroneb Solo nebulizer system requires continued operation during power mains interruption, it is recommended that the Aeroneb Solo nebulizer system be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: Ut is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity for a system that is not life supporting

This Aeroneb Solo nebulizer system is intended for use in the electromagnetic environment specified below. The customer or the user of the Aeroneb Solo nebulizer system should assure that it is used in such an environment.

Immunity Test	IEC/EN 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the USB Controller System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance**
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	d = [1.17] √P d = [1.17] √P... 80MHz to 800MHz d = [2.33] √P... 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in Watts (W)
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the USB Controller System is used exceeds the applicable RF compliance level above, the USB Controller System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the USB Controller System.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m

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